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EXAMINER	
CHO, DAN SUNG C	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,322	JAMES ET AL.	
	Examiner	Art Unit	
	Dan-Sung C. Cho	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-8,16-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5 and 9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/2006, 1/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-33 are pending. Support for the amendment filed on 10/18/2006 is found at page 25, line 25 to page 26 of the specification.

Specification Objections

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, page 99, line 23. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

Election/Restrictions

3. Applicant's election with traverse of Group I, Claims 1-24 and election of SEQ ID NO; 7 in the paper filed 10/18/2006 is acknowledged.

Applicant asserts that Groups I and II should be rejoined because the two groups are "clearly related and are not "independent and distinct". This arguments have been thoroughly reviewed but were not found persuasive.

Although inventions I and II are related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different

classification, restriction for examination purposes as indicated is proper. In addition searching them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. Groups I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together. Therefore, the restriction is proper and made FINAL.

Claims 2-4 and 6-8, 16-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Priority

4. This application claims priority as a CON of PCT/AU02/01258, filed on 09/13/2002 which claims benefit of 60/322,288, filed on 09/14/2001. However, SEQ ID NO: 7 of the instant application and SEQ ID NO: 7 of PCT/AU02/01258 differ by a nucleotide. Further, the sequence of SEQ ID NO: 7 is not taught in the '288 application. Therefore, the instant applicant's effective filing date is the filing date of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 5, and 9-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain a subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1, 5, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the overexpression of SEQ ID NO: 7 in an individual with colorectal adenoma in colorectal biopsy sample as an indication of colorectal adenoma marker, does not reasonably provide enablement for a use of overexpression of any other SEQ ID NO: 7 related sequences in human colorectal adenoma or SEQ ID NO: 7 and its related sequences in any other types of adenoma in any other samples in other non-human individuals as an indication of the onset or predisposition to the onset of neoplasm.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 1, 5, and 9-15 broadly encompass a method of determining the onset or a predisposition to the onset of a neoplasm in an individual with a marker DNA SEQ ID NO:7 or its related sequences. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

"A nucleotide sequence capable of hybridizing to any one or more of the sequences" of SEQ ID NO:7 "under low stringency conditions at 42°C", encompasses many nucleic acids that would hybridize to SEQ ID NO:7 or its homolog or a variant or a homologue. However, the specification discloses one DNA sequence with the asserted function as a neoplasm marker in human. For example, a 12-mer oligonucleotide with the sequences of 5'-TTTTTTTTTTTT-3' would hybridize to SEQ ID NO:7 positions 3660-3671 under the recited condition; however the recited 12-mer can be hybridized to a majority of genes with poly(A) tails in any animal or individual.

"Individual" is a broad term that includes human, dog, cat or other higher animals. However, whether all these animals have the SEQ ID NO: 7 or its related nucleic acid as set forth in the instant claims is not clear. The specification teaches a sequence with the asserted function as a neoplasm marker in human but not in any other individuals.

"Biological sample" is a broad term that includes any samples including urine, hair, prostate, breast, etc. However, the specification does not teach overexpression of SEQ ID NO:7 functional derivatives, any variants or homologs of SEQ ID NO:7 in any other tissue except colorectal tissue. The specification teaches the sequence is from a human colorectal biopsy sample (page 97, line 4) but does not teach any other source

in human and any source of sampling in other non-human individuals that this sequence is overexpressed in other neoplasms.

"Neoplasm" is a also a broad term that includes any neoplasm on any types tissues and organs. However, the specification only teaches overexpression of the SEQ ID NO: 7 sequence in colorectal neoplasm. The specification does not teach overexpression of SEQ ID NO:7 functional derivatives, variants or homologs in colorectal neoplasm or SEQ ID NO:7 and its related nucleic acids in any other types of neoplasms as set forth in the instant claims. The specification teaches the adenoma biopsy samples from human patients with adenomas undergoing colonoscopy. The specification does not teach any other source in human or other types of adenoma and any source of sampling or types of adenoma in other non-human individuals. Many transcripts are tissue- and tumor-specifically expressed at different levels. For example CD44v expression level is high in all metastatic brain tumors but virtually negative in tumors metastatic to the spine (Resnick et al., 1999, Molecular Diagnosis, 4: 219-232).

The unpredictability of the art and the state of the prior art

High expression of Prostate specific membrane antigen (PSMA) in more aggressive prostate cancer makes PSMA a potential diagnostic target for prostate cancer (Schmittgen et al., Int. J. Cancer, 2003, 107:323-329). PSMA has three alternatively spliced variants, PSM', PSM-C and PSM-D. When PSMA and the alternatively spliced variant levels were compared by qPCR methods in various samples of normal, benign, primary and metastatic tissues from much larger sample size of 72 patients, however, the results indicate complex and contradictory expression profiles of the splice variants

quite different from the initial PSMA expression patterns (Table III). For example although PSMA mRNA levels were seen increased 3-fold in primary prostate tumor, bone and lymph node metastases samples compared to normal prostate it was not increased in liver metastases samples but in fact decreased slightly. Therefore an increased PSMA mRNA expression level may be a marker for prostate tumor, bone and lymph node metastases but not for liver metastases. Additionally, not all PSMA variant transcripts showed increased expression levels in prostate tumor as the splice variants PSM-D expression level is not increased but rather decreased. PSM-D mRNA level, on the other hand, is increased in other types of tissues such as bone and lymph node metastases samples. Therefore the art teaches the use of a marker for disease risk assessment is unpredictable depending on the variants, biological sample and sources, and types of neoplasm.

Guidance in the Specification.

The specification does not provide any evidence that an increased expression of SEQ ID NO: 7 related sequences can be used as a neoplasm marker for all types of neoplasms in all kinds of individuals with all kinds of biological samples other than the sequence of the SEQ ID NO: 7. The specification teaches human patients with colorectal adenoma (Examples I). However, the specification does not teach any other examples in any other tissue, neoplasm or nucleic acids comprising of SEQ ID NO: 7 sequences with deletions, additions, substitutions and variants, homologues, functional derivatives or guidance as to what sequences or features of SEQ ID NO: 7 sequences or its variants, homologues, functional derivatives sequences would hybridizes to SEQ ID NO: 7 and would meet all the limitations of the instant broad claims where such a

nucleic acid can be used to determine the onset or a predisposition to the onset of any neoplasm in any individual by measuring elevated expression levels of the sequence.

The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention.

Working Examples

The specification only teaches association of increased SEQ ID NO: 7 expression in colorectal adenoma human patients (Example 1) but not in other types of individuals or other types of tissues or neoplasm or SEQ ID NO: 7 variants, functional derivatives, homologs and other sequence-related nucleic acid molecules.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied such as detection of elevated expression of SEQ ID NO: 7 functional derivatives, variants, functional derivatives, homologs and other SEQ ID NO: 7 sequence-related nucleic acid molecules with all types of neoplasms in all types of individuals that meets the limitations of the instant claims and determine if each sequence expression level increase in all types of patients and tissues can be used as a marker for the onset or a predisposition to the onset of any neoplasm in any individual. This would require extensive experimentation and specific guidance, with many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps, which are not routine, and an artisan of skill would not have known at the time of invention.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where an increased expression of a DNA marker is asserted to be associated with neoplasma patient, the specification provides a single example and no guidance to support the limitation of the instant claims wherein overexpression of any SEQ ID NO: 7 functional derivatives, variants, functional derivatives, homologs and other SEQ ID NO: 7 sequence-related nucleic acid molecules can be used as a neoplasm marker.

Further, the prior art and the specification provides insufficient guidance to overcome the art recognized unpredictability of different expression patterns for splice variants. Therefore the use of splicing variants are unpredictable as marker sequences. for all types of neoplasms in various tissues and sample sources. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 5, and 9-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of determining the onset or a predisposition to the onset of a neoplasm in an individual comprising measurement of the level of expression of a nucleic acid, (a) comprising SEQ ID NO:7; (b) any nucleic acid sequence capable of hybridizing to SEQ ID NO:7 under low stringency conditions at 42°C; or any a functional derivative, variant or homologue of (a) or (b), in any biological sample wherein any increase in the level of expression of the sequences relative to the normal level of expression is indicative of the onset or predisposition of the onset of any neoplasm in any individual. The broad genus encompassed by the claims includes the recited nucleic acids of any species such as rat, dog, cat, etc., as well as SEQ ID NO: 7 variants, functional derivatives, homologs and other SEQ ID NO: 7 sequence-related nucleic acid molecules.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In The Regents of the University of California v. Eli Lilly (43.

USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B (1), the court states that "An adequate written description of a DNA. . .' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention.

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure.

With regard to "individual", the specification does not teach any structure of SEQ ID NO:7 in dogs, cats and in other organisms, nor does it provide any guidance as to the structure of such sequences in other individuals other than to the sequence from human colorectal tissue.

With regard to "a functional derivative, variant or homologue", the specification does not teach any structure of a DNA sequences that would be a functional derivative, variant or homologue of the human SEQ ID NO:7 or a sequence that hybridizes to SEQ ID NO:7 under a low stringency conditions, in any individual, nor does it provide any guidance as to the structure of such sequences in any individual. Many alternative splicing variants, for example, encode proteins with vastly different function, localization

and expression. Two functionally disparate PSMA and PSM' polypeptides with differential cellular localization are generated from the protein-coding sequences of the same gene. The expression levels of the two functional derivatives from splicing variants of the same gene are different depending on tissue-type and tumor-type as explained above (Schmittgen et al., page 323, right column, paragraph 1). Therefore, sequence variants or homologs may have vastly different functions and expression patterns and levels and therefore may not be used as markers for the same biological functions such as onset or predisposition of neoplasm. In addition, functional derivatives of PSMA alternative transcripts as described above exemplify that functional derivatives have tissue- and tumor-specific expression levels. For example, translation of PSM-C mRNA results in a protein that is identical to PSM' and therefore with identical function; however, the expression levels of the two transcripts are quite different. The expression levels of bone metastases PSM-C is increased approximately 2-fold but the identical transcripts that encode identical proteins is seen decreased in the samples. Therefore even two transcripts that encode identical proteins with identical function can have differential expression patterns depending on tissue and tumor types.

With regard to "a nucleotide sequence capable of hybridizing to any one or more of the sequences" of SEQ ID NO:7 "under low stringency conditions at 42° C and SEQ ID NO: 7 functional derivatives, variants and homologs, the specification does not teach any structure of a DNA sequences that would hybridize to SEQ ID NO:7 under the recited low stringency condition in any individual, nor does it provide any guidance as to the structure of such sequences in any individual. For example, a 12-mer

oligonucleotide with the sequences of 5'-TTTTTTTTTTTT-3' would hybridize to SEQ ID NO: 7 positions 3660-3671 under the recited condition; however the recited 12-mer can be hybridized to a majority of genes with poly (A) tails. Therefore increased expression of a nucleic acid sequence, comprised of SEQ ID NO: 7, such as any poly (A) tail containing sequence, does not appear to make such a sequence a neoplasm marker.

Next, it is determined whether other identifying characteristics have been described that will describe other members of the genus. In the instant case none of the identifying characteristics have been described. The specification teaches the human sequence SEQ ID NO: 7 but no identifying characteristics that can be used to identify other sequences encompassed by the broad instant claims as neoplasm marker when overexpressed. Therefore, the specification does not teach any relevant identifying characteristics of a representative number of species within the claimed genus to identify a nucleic acid sequence when overexpressed can be used as a neoplasm marker.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics of SEQ ID NO: 7 in other organisms and sequences or features of sequences comprised of SEQ ID NO: 7 that identify members of the genus, and because the genus is highly variant, and the specification fails to describe specific species of the genus of the neoplasm marker in non-humans and other sequences in human than the single species of SEQ ID NO: 7 disclosed and without any guidance to structure/function relationship to determine if a

nucleic acid identified would be a useful neoplasm marker, one of skill in the art would conclude that applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1, 5, and 9-15 are rejected under 35 U.S.C. 102 (a and e) as being anticipated by James (James et al., 2002, PCT/AU02/01258).

With regard to claims 1, 5 and 9-15, James teaches a method of measuring SEQ ID NO:7 which has 99% sequence identity to SEQ ID NO: 7 of the instant application (Sequence alignment provided) as a colorectal neoplasm marker. James teaches a method of measuring and comparing expression levels of many genes including SEQ ID NO:7 in human colorectal biopsy samples of normal and adenoma tissues wherein the sequence is determined to have increased expression levels in human colorectal adenoma samples when compared to normal control samples. (page 97, Example 1).

There is a single nucleotide difference between the two recited sequences at position 3362. In the PCT/AU02/01258, the position has T but R in the instant application. The letter "R" is the symbol for purine or A and G. The two sequences differ

at this position. However claim 1 recites "nucleic acid molecules comprising a nucleotide sequence capable of hybridizing any one or more of the sequences of (i) under low stringency conditions at 42°C or a functional derivative, variant or homologue of said nucleic acid molecule" and SEQ ID NO:7's "functional derivative, variant or homologue of said nucleic acid molecule". Therefore SEQ ID NO:7 of James is a variant and homolog and a functional derivative of SEQ ID NO:7 of the instant application.

With regard to claim 5, James teaches a method of determining expression levels and determining expression level of SEQ ID NO:7, which has 99% sequence homology to SEQ ID NO:7 of the instant application wherein the level of the increase is 45-fold (See Rank #5, Clone 12-2f, which is SEQ ID NO:7; page 115, Table 3).

8. Claims 1, and 9-13 are rejected under 35 U.S.C. 102 (b) as being anticipated by Loiseau et al. (Loiseau et al., Neuroscience Letter, 1999, 263: 173-176).

With regard to claims 1 and 9-13, Loiseau teaches a method of detecting p73 gene transcripts. Claim 1 broadly encompasses any variation sequence. p73 gene transcripts Loiseau teaches is broadly interpreted as a sequence variant of SEQ ID NO: 7. Loiseau teaches a method of measuring and comparing expression levels of human p73 gene in various histological types of human central nervous system tumors: neurinomas, medulloblastomas, meningiomas, metastases, astrocytomas grade I–IV, and ependymomas compared to normal control samples by semi-quantitative RT-PCR and found that it is over-expressed in many of the tumors (page 175, Figure 1).

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Dan-Sung C. Cho whose telephone number is (571) 272-9933. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The Central Fax Number for official correspondence is (571) 273-8300.

Dan-Sung C. Cho
Examiner

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER
2/5/07